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FOREWORD

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1. INTRODUCTION

1.1. Background

Breast cancer incidence rates in the San Francisco Bay Area are among the highest in the world [1]. In 1994, breast cancer affected 125.1 per 100,000 white women, the racial-ethnic group with the highest incidence rate, and as the leading incident cancer in women accounted for 33% of all cancers diagnosed in women [2]. Although incidence rates (per 100,000) are lower in African-Americans (96.3), Latinas (74.3), and Asians (68.0), breast cancer is the leading cancer in these populations as well [2].

The pronounced racial-ethnic differences in breast cancer incidence between Latinas, African-Americans, and white women remain largely unexplained for several reasons: (1) Few analytic studies with an etiologic focus have been conducted in Latina and African-American populations [3-11]; (2) few breast cancer studies included non-white populations that were large enough for separate analysis and racial-ethnic comparisons of risk factors [5,7,8]; and (3) in the few studies that included African-American women only [3,4,6,9-11], the comparison of risk factors with those of other racial-ethnic groups is limited by differences in methodology and data collection instruments used in different studies. It therefore is not known to what extent the differences in incidence rates are attributable to racial/ethnic differences in (1) the magnitude of relative risks associated with known and suspected risk factors, (2) the prevalence of known and suspected risk factors, (3) the magnitude of relative risks and/or prevalence of risk factors yet to be identified, and (4) genetic susceptibility.

1.2. Purpose of On-going Research

The San Francisco Bay Area offers a unique opportunity to conduct etiologic research in a multiracial/ethnic population given the large number of breast cancer cases diagnosed each year, 25% of whom are non-white. The on-going population-based case-control study is collecting interview data for African-American and white breast cancer cases and population controls. It uses the same protocol and data collection instruments as two complementary case-control studies that are on-going, one of which includes Latina women only (PI: Dr. Esther M. John), and the second of which includes Latina, African-American, and white women (PI: Dr. Pamela Horn-Ross). The three studies are administered as one single case-control study.

The purpose of the on-going study is to collect interview data on a broad array of known, suspected, and newly hypothesized factors, with the ultimate goal of pooling the data from the three case-control studies. The pooled data will allow us to examine racial/ethnic differences in breast cancer risk factors in a large multiracial/ethnic population from a single geographic area. This research will make a significant contribution to the lack of knowledge about the etiology of breast cancer in non-white populations and will help elucidate the reasons for the striking racial/ethnic differences in breast cancer incidence.

2. BODY

2.1. Research Materials and Methods

2.1.1. Study population

Cases include women meeting the following eligibility criteria: (1) newly diagnosed with histologically confirmed, primary invasive breast cancer; (2) no previous history of breast cancer; (3) African-American or white (based on self-identification), aged 35-49 years at diagnosis, and diagnosed between April 1, 1995 and July 31, 1998; (4) African-American or white (based on self-identification) aged 50-79 years at diagnosis, and diagnosed between April 1, 1995 and June 30, 1995 or between November 1, 1996 and July 31, 1998; (5) alive at the time of contact; (6) residing in Alameda, Contra Costa, San Francisco, San Mateo, or Santa Clara counties, California, at the time of diagnosis.

Women with newly diagnosed breast cancer are identified through the two population-based cancer registries operated by the Northern California Cancer Center. Confidential information on newly diagnosed breast cancer cases is obtained from the registries about every 6 weeks. Based on recent registry data, we anticipate that 500 African-American and 5,100 white breast cancer patients will be eligible for the on-going study. All African-American women and a 10% random sample of white women are invited to participate in the interview. After excluding cases who are deceased or have a personal history of breast cancer, interviews are expected to be completed for 733 cases (347 blacks and 386 whites).

Controls include a probability sample of women who meet the following criteria: (1) No previous history of breast cancer; (2) alive and between the ages of 35 and 79 years at the time of selection into the study; (3) residing in Alameda, Contra Costa, San Francisco, San Mateo, or Santa Clara counties, California, at the time of selection into the study; (4) African-American or white based on self-identification.

Controls are identified through random-digit-dialing (RDD). A bank of 70,000 random numbers has been established for the three on-going case-control studies. The random numbers are called by four telephone specialists in monthly waves of 2,200 (even months) or 2,800 (uneven months) numbers. After completion of each wave, controls are randomly selected into the study from the pool of eligibles. Controls are frequency-matched to cases by race (African-American, white) and five-year age group (35-39, 75-70). Equal number of case and control interviews will be completed.

2.1.2. Data collection procedures

Data collection is performed by experienced professional interviewers and involves a brief screening interview administered over the telephone and an in-person interview usually administered at the participant's home. The screening interview inquires about current age, racial/ethnic background, adoption status, Jewish heritage, personal history of breast or ovarian cancer, and history of cancer in first-degree relatives. The in-home interview involves the administration of the consent form, a structured questionnaire, and the measurement of weight, height, waist and hip circumference, and skin pigmentation using a Minolta Chromameter. The questionnaire inquires about demographic background, physical activity, sunlight exposure, diet, supplement intake, anthropometry, residential history, occupational history, pregnancy history, menstrual history, hormone use, and medical history.

2.1.3. Data management

Progress in RDD and data collection (e.g., screening, in-person interview, measurements) is monitored through two computerized FOXPRO tracking systems. Data entry of screening and questionnaire data is also performed through FOXPRO data entry screens.

2.2. Progress of On-going Data Collection

2.2.1. Data collection instruments

Data collection was able to start immediately following the receipt of the award since data collection for the two complementary studies that use the same protocol was already on-going by July 1996.

The screening and in-person questionnaires had been developed and thoroughly pilot tested as part of the two complementary studies.

2.2.2. Interviewers

Additional professional interviewers were hired and thoroughly trained. A two-week training curriculum, an interviewer's manual on interviewing techniques, question-specific instructions, and protocols for the measurements were developed in order to provide standardized training to all interviewers and assure the collection of high-quality and unbiased data.

2.2.3. Completed field work

Cases: As of the end of June 1997, 1,337 newly diagnosed breast cancer cases had been reported to the cancer registry who were listed as African-American or white and who had been diagnosed during the ascertainment period of interest. A 10% random sample of white cases and all African-American cases were eligible for inclusion in the study (N=279). Of these, 13 had a prior diagnosis of breast cancer and 15 cases were deceased at the time of contact, and were therefore excluded from the study. As required by the cancer registries, the physicians of these patients were contacted, and contraindications were given for 4 patients (1.6 % of eligible cases).

Of the 247 remaining cases eligible for contact by the interviewer, 25 have not yet been assigned to the interviewers and 36 are currently being processed. Of the remaining 186 cases, the telephone screening interview has been completed for 156 cases (84%), 28 cases refused to participate (15%), and 2 cases (1%) could not be located.

Among those who completed the screening interview, 125 cases self-identified themselves as African-American or white. Of these, 18 are currently being contacted by the interviewers. Among the remaining 107 cases, 87 (81%) have completed the in-person interview and measurements (including 49 white and 38 African-American cases), whereas 20 refused participation (19%).

Controls: To date, about 30,000 random telephone numbers have been closed out and screened for eligible population controls for the three on-going studies. From the pool of

eligibles, 316 controls were selected into the DOD study. Of these, 25 have not been assigned yet and 56 are currently being processed. A number of controls were excluded during the screening process: 11 had prior breast cancer, 3 did not self-identify themselves as African-American or white, 3 did not speak English or Spanish, 1 was deceased, and 7 had a non-functioning telephone number. Of the remaining 210 eligible controls, 178 (85%) completed the screening interview, whereas 32 (15%) refused participation.

Of the controls eligible for the in-person interview, 31 are currently being contacted by the interviewers. Among the remaining 147 controls, 119 (81%) completed the in-person interview and measurements (including 71 white and 48 African-American controls), whereas 28 (19%) refused participation.

2.2.4. Completed interviews vs. work scope

Of the 1,466 interviews to be completed over the course of the study, 14% of the work was completed during year 1 of the project, which corresponds with the volume of work budgeted for year 1. A total of 700 interviews are scheduled to be completed by the end of year 2 of the project.

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